



Dkt. 71541-A-PCT-US/JPW/DC

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants

: Orna Mor, et al.

U.S. Serial No.

: 10/579,662

Filed

: May 17, 2006

For

: DIAGNOSIS AND TREATMENT OF KIDNEY FIBROSIS AND OTHER FIBROTIC DISEASES

> 1185 Avenue of the Americas New York, New York 10036 June 20, 2007

Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

In order to ensure compliance with applicants' duty of disclosure under 37 C.F.R. §1.56 and §1.97(a)-(d), applicants request that the documents listed on Form PTO-1449, attached hereto as Exhibit A, be considered and made of record in the above-identified application. These documents are the following:

- International Search Report issued by the International Searching Authority (ISA) on November 2. in connection with PCT International Application No. PCT/IL2004/001049 (Exhibit 1);
- International Preliminary Report on Patentability issued by the International Bureau of WIPO on May 22, 2006 in connection with PCT International Application No. PCT/IL2004/001049 (Exhibit 2):
- 3. FANG et al. (2003), "PLD1 Regulates mTOR Signaling and Mediates cdc42 Activation of S6K1," Current Biology, Vol. 13, pages 2037-2044 (Exhibit 3):
- 4. DAY et al. (1993), "Plasma membrane form of phosphotidate phosphohydrolase: a possible role in signal transduction

Applicants: Orna Mor, et al. U.S. Serial No.: 10/579,662 Filed: May 17, 2006 Page 2

during liver fibrogenesis," Clinical Science (London), Vol. 3, pages 281-287 (Exhibit 4);

- MIN et al. (2001), "Altered Expression of Phospholipase D1 in Spontaneously Hypertensive Rats," Molecules and Cells, Vol. 11, No. 3, pages 386-391 (Exhibit 5);
- ZHAO et al. (2000), "Increased Activity and Intranuclear Expression of Phospholipase D2 in Human Renal Cancer," Biochemical Biophysical Research Communications, Vol. 278, pages 140-143 (Exhibit 6);
- COBURN et al. (2003), "siRNAs: a new wave of RNA-based therapeutics," Journal of Antimicrobial Chemotherapy, Vol. 51, pages 753-756 (Exhibit 7);
- PCT International Application Publication No. WO 2003/035083 Al (BAUER et al.), published May 1, 2003 (Exhibit 8);
- U.S. Patent No. 6,187,559 B1, issued February 13, 2001 to STEED et al.

Copies of documents numbers 1-8 are attached hereto as Exhibits 1-8, respectively.

In accordance with 37 C.F.R. \$1.92(a)(2)(ii), copies of U.S. Patents and U.S. Patent Application Publications need not be provided. Accordingly, a copy of document number 9 is not submitted herewith.

Applicants: Orna Mor, et al. U.S. Serial No.: 10/579,662 Filed: May 17, 2006 Page 3

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

John Pl White

hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

P. White

No. 28,678

Registration No. 28,678 Attorney for Applicants Cooper & Dunham, LLP 1185 Avenue of the Americas New York, New York 10036 (212) 278-0400

JUN 9 5 1007

U.S. Palant and Tredement Office U.S. DPARTMENT OF COMMERCE

U.S. Palant and Tredement Office U.S. DPARTMENT OF COMMERCE

Under the Search of 1995, no persons are required to respond to a collection of Informetic unities at containing a valid Under the Comment of Informetic United Search of Informetic United Search of Informetic United Search Office U.S. Description under the United Search Office

Complete if Known SUBJECT form 1449/PTO Application Number 10/579.662 INFORMATION DISCLOSURE Filing Date May 17, 2006 STATEMENT BY APPLICANT First Named Inventor Oma Mor Art Unit (Use as many sheets as necessary) Examiner Name Attorney Docket Number 1 of 2 71541-A-PCT-US/JPW/DC

| Examiner Cit Initials* No | | | |
|------------------------------|--|---|----|
| /AB/ | | International Search Report issued by the International Searching Authority (ISA) on November 2, 2005 in connection with PCT International Application No. PCT/IL2004/0010 | |
| | | International Preliminary Report on Patentability issued by the International Bureau of WiPO on May 22, 2006 in connection with PCT international Application No. PCT/IL2004/001049 | |
| | | FANG et al. (2003), "PLD1 Regulates mTOR Signaling and Mediates cdc42 Activation of S6K1," Current Biology, Vol. 13, pp. 2037-2044 | |
| | | DAY et al. (1993), "Plasma membrane form of phosphotidate phosphohydrolase: a possible role signal transduction during liver fibrogenesis," Clinical Science (London), Vol. 3, pages 281-287 | in |
| | | MIN et al. (2001), "Altered Expression of Phospholipase D1 in Spontaneously Hypertensive Rats," Molecules and Cells, Vol. 11, No. 3, pp. 386-391 | |
| | | ZHAO et al. (2000), 'Increased Activity and intranuclear Expression of Phospholipase D2 in Hum Renal Cancer," <i>Biochemical Biophysical Research Communications</i> , Vol. 278, pages 140-143 | an |
| | | COBURN et al. (2003), "siRNAs: a new wave of RNA-based therapeutics," Journal of Antimicrobial Chemotherapy, Vol. 51, pp. 753-756 | |
| \bigvee | | PCT International Application Publication No. WO 2003/035083 A1 (BAUER et al.), published May 1, 2003 | |
| | | | |
| | | | T |

| Examiner Signature | /Amy Bowman/ | Date Considered | 11/25/2008 |
|-----------------------|--------------|--------------------|------------|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

considerate. Include cuty or instrum with next communication to appearant.

A polipharities to piece a price of the communication of th

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

PTO/SB/08A (04-07)

Approved for use through 09/30/2007. OMB 0651-0031
U.S. Petent end Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of Information unless it contains a valid OMB control number

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) of

Complete if Known Application Number 10/579,662 Filing Date May 17, 2006 First Named Inventor Orna Mor Art Unit Examiner Name Attorney Docket Number 71541-A-PCT-US/JPW/DC

| U. S. PATENT DOCUMENTS | | | | | | |
|------------------------|--------------|---|--------------------------------|--|---|--|
| Exeminer Initiels* | Cite No.1 | Document Number Number-Kind Code ^{2 (F incomp)} | Publication Date MM-DD-YYYY | Name of Patentae or Applicant of Cited Document | Pages, Columns, Lines, Whare Relevant Passages or Relevant Figures Appear | |
| /AB/ | | ^{US-} 6,187,559 B1 | 02-13-2001 | Steed et al. | Column 21, lines 23-34 | |
| | | US- | | | | |
| | | US- | | | | |
| | | US- | | | | |
| | | US- | | | | |
| | | US- | T | | | |
| | | US- | | | | |
| | | US- | | | | |
| | | US- | | | | |
| | <u> </u> | US- | | | | |
| | _ | US- | | | | |
| | | UŞ- | | | | |
| | | US- | | | | |
| | | US- | | | _ | |
| | | US- | | | | |
| | | US- | | | | |
| | | US- | | | | |
| | | US- | | | | |
| | | US- | + | | | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|--------------------------|--|-----------------------------|--|---|----|
| Exeminer initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Petentee or Applicant of Cited Document | Peges, Columns, Lines, Where Relevent Passages Or Relevant Figures Appear | т. |
| | | Country Code ³ "Number ⁴ "Kind Code ⁹ (# known) | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | L |
| | | | | | | |
| | - | | | | | ட |
| | | | | | | _ |

| Examiner Signeture | /Amy Bowman/ | Date Considered | 11/25/2008 |
|-----------------------|--------------|--------------------|------------|

"EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered, include copy of this form with next communication to applicant. "Applicants unique citation designation number (optional). "See Kinds Codes of USPTO Petant Occurrents at whether conformation is the conformation of the Empiricant procedule to senting number of the patent document. "Kind of document by the conformation of the conformation of the conformation of the Communitaries of Title of possible. "Applicants to give one on the communitaries and Procedule and Conformation of the Communitaries of Title of possible." "Applicants to give one on the communitaries and Procedule and Conformation of the Communitaries Translation is attached.

Translation is attached. This collection of the public which is to file (end by the Translation is required by 7 CFR; 107 mot 1.98. The information is required to obtain or retain a benefit by the public which is to file (end by the public properties). Confidentish is a seemed, Total CFR; 11.14. This collection is estimated to take 2 hours to complete, including opthering, preparing, and submitting the completed application form to the aDTC TR. 1.14. This collection is estimated to take 2 hours to complete including opthering, preparing, and submitting the completed application form to the aDTC TR. 1.14. This collection is estimated to take 2 hours to complete including opthering. Properties of the complete the form and/or suggestions for reducing this budget, should be sent to the Cflir information Office. Or Commission for Patients, P.O. Sox 1450, Alexandric, VA 2231-1450, B.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.